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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,692	08/14/2001	Jim J. McGhan	011111	3354

7590

01/30/2004

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EXAMINER

MILLER, CHERYL L

ART UNIT PAPER NUMBER

3738

DATE MAILED: 01/30/2004

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,692

Applicant(s)

MCGHAN, JIM J. *cl*

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4,6,8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4,6,8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 10, 2003 has been entered.

It is noted to the applicant that the request for continued examination submitted was non-compliant due to an absence of a complete listing of all claims present in the application, including claims that have been withdrawn and cancelled. Although the RCE was non-compliant, the preamendment has been entered anyway, since it was easily understandable by the examiner. In future instances, amendments to the claims must be submitted on a separate page with a complete listing of all the claims.

Response to Arguments

Applicant's arguments with respect to claims 2, 4, 6, 8, and 11 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 6, 8, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Several issues are unclear with respect to claim 2. The first

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issue is that it is unclear as to what is the "outer surface" as applicant has claimed. Is the outer surface the smooth top surface of the core (only inbetween the particles), or the entire top surface of the core (smooth top surface, plus topmost surface of the indentations where the particles would be located), or the top surface of the implant, which includes the smooth top surface of the core and top outlining surface of the particle protrusions. It is asked that the applicant please specify, since the surface only has an irregular topography if the applicant is talking about the surface of the core plus the particle protrusions. The second issue is that it is unclear as to if the bioabsorbable portion is the same or different from the plurality of particles of bioabsorbable material. If the particles are indeed part of the portion, it is suggested to change "wherein a plurality of particles of a bioabsorbable material is embedded" to recite --wherein the bioabsorbable portion comprises a plurality of particles of a bioabsorbable material embedded--.

Claim 2 recites the limitation "said outer surface of said hybrid medical implant" in line 6. There is insufficient antecedent basis for this limitation in the claim. Applicant has claimed the core portion having an outer surface, however not the implant having an outer surface (which is a different surface due to the presence of the particles). Claims 4, 6, 8, and 11 depend upon claim 2 and inherit all problems associated with the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 4, 6, 8, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Harish et al. (USPN 6,506,437 B1, cited in previous office action). Referring to claim 2, Harish discloses a hybrid medical implant (10) comprising an elastomeric, non-bioabsorbable core portion (12, biostable polymers, col.4, lines 5-9; col.5, lines 44-49) having an outer surface (20) and a bioabsorbable portion (30, 34) affixed to the outer surface (20) of the core portion (12), wherein a plurality of particles (34, of particles in 30, 34, col.6, lines 45-48) of bioabsorbable material are embedded in the outer surface (20) of the core (12) and wherein the outer surface of the implant has an irregular topography (fig.6B, 7B, 9B, 9C), such that upon implantation of the implant, the plurality of particles of material project outwardly from the outer surface and after the bioabsorbable material is absorbed, the outer surface has a plurality of craters there within.

Referring to claim 4, Harish discloses a core portion (12) comprising a fluid-filled elastomeric (col.4, lines 5-9; col.5, lines 44-49) shell (the core is filled with air initially, and filled with blood, once placed in the vessel).

Referring to claim 6, Harish discloses a solid elastomeric body (12; viewing the core as a sheet, or viewing a section of the core, the cross section of the core is a solid body).

Referring to claim 8, Harish discloses an elastomeric core comprising silicone (biostable polymers, col.4, lines 5-9; silicone listed as an example of biostable polymers, col.5, lines 44-49).

Referring to claim 11, Harish discloses a bioabsorbable portion (30, 34) comprising an antibiotic (col.2, lines 36-43; col.3, line 45-col.7, line 52).

Claims 2, 4, 6, and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Durgin (Pub.No. US 2002/0052653 A1). Referring to claim 2, Durgin discloses a hybrid medical implant (fig.3, 12) comprising an elastomeric, non-bioabsorbable core portion (30, 30A; 0050) having an outer surface and a bioabsorbable portion (32, 32A) affixed to the outer surface of the core portion (30, 30A), wherein a plurality of particles (32, 32A) of bioabsorbable material (0056) are embedded in the outer surface of the core (30, 30A, fig.3, 12) and wherein the outer surface of the implant has an irregular topography (fig.3, 12), such that upon implantation of the implant, the plurality of particles of material project outwardly from the outer surface and after the bioabsorbable material is absorbed, the outer surface has a plurality of craters there within (0055, 0056).

Referring to claim 4, Durgin discloses a core portion (30, 30A) comprising a fluid-filled elastomeric shell (0052).

Referring to claim 6, Durgin discloses a solid elastomeric body (0051).

Referring to claim 8, Durgin discloses an elastomeric core comprising silicone (0050).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marotta et al. (USPN 6,299,930 B1) in view of Melican et al. (USPN 6,599,323 B2). Referring to claim 2, Marotta discloses a hybrid medical implant comprising an elastomeric, non-

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bioabsorbable core portion (substrate, col.3, lines 65-67; col.4, lines 5-8) having an outer surface and a second portion (bioactive component) affixed to the outer surface of the core portion, wherein a plurality of particles of material are embedded in the outer surface of the core (col.4, lines 24-27, 40-43) and wherein the outer surface of the implant has an irregular topography (fig.1), such that upon implantation of the implant, the plurality of particles of material project outwardly from the outer surface (fig.1). Marotta discloses the second portion, comprising the plurality of particles to be glass particles, specifically BIOGLASS. Marotta is silent to mention however, the particles to be bioabsorbable. Melican teaches in the same field of hybrid medical implants, that BIOGLASS is a bioabsorbable material (col.7, lines 3-8), and that it is useful in implants to reinforce initially and later absorb, forming pores or craters for ingrowth (col.8, lines 25-35, 52-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Melican's teaching that BIOGLASS is bioabsorbable, with Marotta's hybrid implant having an elastomeric core and BIOGLASS particles embedded in the outer surface, in order to conclude that Marotta's BIOGLASS in the implant is also bioabsorbable, which provides initial reinforcement, and pores later for ingrowth and attachment.

Referring to claim 6, Marotta discloses a solid elastomeric body (fig.1).

Referring to claim 8, Marotta discloses an elastomeric core comprising silicone (col. 5, lines 30-31, 44, 46; col.8, lines 7-10, 25-26).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER